



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0441; FRL-9372-9]

Difenzoquat; Data Call-in Order for Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final order.

SUMMARY: This order requires the submission of various data to support the continuation of the tolerances for the pesticide, difenzoquat. Pesticide tolerances are established under the Federal Food, Drug, and Cosmetic Act (FFDCA). Following publication of this order, persons who are interested in the continuation of the difenzoquat tolerances must notify the Agency by completing and submitting the required section 408(f) Order Response Form (available in the docket) within 90 days. If the Agency does not receive within 90 days after publication of the final order a section 408(f) Response Form identifying a person who agrees to submit the required data, EPA will revoke the difenzoquat tolerances.

DATES: This final order is effective [*insert date of publication in the Federal Register*]. A section 408(f) Order Response Form must be received on or before [*insert date 90 days after date of publication in the Federal Register*].

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2012-0441. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or

other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

Submit your section 408(f) Order Response Form, identified by docket identification (ID) number EPA–HQ–OPP–2012-0441, by one of the following methods:

- *Federal eRulemaking Portal*: Follow the on-line instructions for submitting comments.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., N.W., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

FOR FURTHER INFORMATION CONTACT: Christina Scheltema, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection

Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-2201; e-mail address: *scheltema.christina@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at

<http://ecfr.gpoaccess.gov/cgi/t/text/text->

[idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the harmonized test

guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines,” which is listed under “Documents related to our mission.”

II. Background

A. What Action is the Agency Taking?

In this document EPA is issuing an order requiring the submission of various data to support the continuation of the difenzoquat tolerances at 40 CFR 180.369, under section 408 of FFDCA, 21 U.S.C. 346a. Difenzoquat is not currently registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The last FIFRA registration for difenzoquat was canceled in 2010. However, 25 FFDCA tolerances remain for residues of difenzoquat on the following commodities: Barley, cattle, goat, hog, horse, poultry, sheep, and wheat (40 CFR 180.369). Because there are currently no domestic registrations for difenzoquat, these tolerances are referred to as “import tolerances.” It is these tolerances that are addressed by the Data Call-In order.

B. What is the Agency's Authority for Taking this Action?

Under section 408(f) of the FFDCA, EPA is authorized to require, by order, submission of data “reasonably required to support the continuation of a tolerance” when such data cannot be obtained under the Data Call-In authority of FIFRA section 3(c)(2)(B), or section 4 of the Toxic Substances Control Act (“TSCA”), 15 U.S.C. 2603. A FFDCA section 408 Data Call-In order may only be issued following publication of notice of the order and a 60-day public comment provision.

A section 408(f) Data Call-In order must contain the following elements:

1. A requirement that one or more persons submit to EPA a notice identifying the person(s) who commit to submit the data required in the order.
2. A description of the required data and the required reports connected to such data;
3. An explanation of why the required data could not be obtained under section 3(c)(2)(B) of FIFRA or section 4 of TSCA.
4. The required submission date for the notice identifying one or more interested persons who commit to submit the required data and the required submission dates for all the data and reports required in the order (21 U.S.C. 346a(f)(1)(C)).

EPA may by order modify or revoke the affected tolerances if any one of the following submissions is not made in a timely manner:

1. A notice identifying the one or more interested persons who commit to submit the data.
2. The data itself.
3. The reports required under a section 408(f) order are not submitted by the date specified in the order (21 U.S.C. 346a(f)(2)).

C. What Preliminary Steps Were Taken by EPA Prior to Issuing this Final Order?

On July 6, 2012 (77 FR 44181) (FRL-9352-9), EPA issued a proposed Data Call-In order for the pesticide difenzoquat in connection with tolerances for that pesticide under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. The proposed Data Call-In order included the following studies:

- Neurotoxicity Screening Battery (870.6200).
- Immunotoxicity Study (870.7800).

- Crop Field Trials (860.1500) – (wheat hay, wheat forage, and barley hay).

III. Summary of Public Comments Received and Agency Response to Comments

EPA received no comments in response to the July 6, 2012, **Federal Register** notice announcing the Agency's proposed Data Call-In order for difenzoquat. In addition, the Agency has not received any of the data identified in the proposed order as needed to support the difenzoquat tolerances.

IV. Final Data Call-in Order

Because no comments were submitted on the proposal and the data deficiencies identified in the proposed order remain, EPA is issuing this final Data Call-In order under FFDCA section 408(f)(1)(C) for difenzoquat in the same form as the proposed order and for the reasons set forth in that proposed order. Specifically, this order:

1. *Requires notice of intent to submit data.* A notice identifying the person or persons who commit to submit the data and reports in accordance with Unit IV.2. must be submitted to EPA if any person wishes to support the difenzoquat tolerances. The notice must be submitted on a section 408(f) Order Response Form which is available in the electronic docket, <http://www.regulations.gov>, under docket ID number EPA–HQ–OPP–2012-0441.

2. *Establishes a deadline for submission of notice identifying data submitters.* The notice described in Unit IV.1., identifying data submitters, must be submitted to and received by EPA on or before [*insert date 90 days after date of publication in the Federal Register*]. Instructions on methods for responding to this order (referred to in this order as a “section 408(f) Order Response Form”) are set out under the **ADDRESSES** section above.

3. *Describes data and reports required to support continuation of the difenzoquat tolerances, requires submission of those data and reports, and establishes deadlines for submission.* The table in this Unit describes the data and reports required to be submitted on difenzoquat under this order and the deadlines for the submission of each study and report. The required submission date is calculated from *[insert date 90 days after date of publication in the **Federal Register**]*. Thus, for example, if EPA generally allows 12 months to complete a study, the required submission date for such a study under this order would be 15 months from the date of publication of the order in the **Federal Register**. Studies, study protocols, and reports should be submitted to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Table--Data and Reports Required to be Submitted on Difenzoquat

OCSPP Harmonized Guideline Number	Study Title	Timeframe for protocol report submission	Timeframe for data submission
870.6200	Neurotoxicity Screening Battery	Not Required	March 19, 2015
870.7800	Immunotoxicity Study	6 months	March 19, 2014
860.1500	Crop Field Trials (wheat hay, wheat forage, and barley hay)	Not Required	March 19, 2015

EPA provided a description of why the required data could not be obtained under section 3(c)(2)(B) of FIFRA or section 4 of TSCA in the proposed order and relies on that description in this final order.

V. Failure to Submit Notice of Intent to Submit Data or Data and Reports

If, by [insert date 90 days after date of publication in the ***Federal Register***] the Agency does not receive a section 408(f) Order Response Form identifying a person who agrees to submit the required data, EPA will revoke the difenzoquat tolerances at 40 CFR 180.369. Such revocation is subject to the objection and hearing procedure in FFDCA section 408(g)(2) but the only material issue in such a procedure is whether a submission required by the order was made in a timely fashion.

Additional events that may be the basis for modification or revocation of difenzoquat tolerances include, but are not limited to the following:

1. No person submits on the required schedule an acceptable protocol report when such report is required to be submitted to the Agency for review.
2. No person submits on the required schedule acceptable data as required by the final order.

VI. Statutory and Executive Order Reviews

This action, which requires the submission of data in support of tolerances in accordance with FFDCA section 408, is in the form of an order and not a rule (21 U.S.C. 346a(f)(1)(C)). Under the Administrative Procedures Act (APA), orders are expressly excluded from the definition of a rule (5 U.S.C. 551(4)). Accordingly, the regulatory assessment requirements imposed on a rulemaking do not apply to this action, as explained further in the following discussion.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Because this order is not a “regulatory action” as that term is defined in Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not subject to review by the

Office of Management and Budget (OMB) under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act

This action does not impose additional burdens that require approval by OMB under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). The information collection activities associated with the order requesting data from any party interested in supporting certain tolerances are already approved by OMB under OMB Control No. 2070-0174, and are identified by EPA ICR No. 2288.01. Burden is defined at 5 CFR 1320.3(b). Under the PRA, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable.

C. Regulatory Flexibility Act

Since this order is not a rule under the APA (5 U.S.C. 551(4)), and does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

D. Unfunded Mandates Reform Act; Executive Order 13132: Federalism; and Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This order requests data from any party interested in supporting certain tolerances and does not impose obligations on any person or entity including States or tribes; nor

does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132 (64 FR 43255, August 10, 1999) and Executive Order 13175 (65 FR 67249, November 9, 2000) do not apply to this order. In addition, this order does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531-1538).

E. Executive Orders 13045: Protection of Children from Environmental Health Risks and Safety Risks; Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use, and Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations

As indicated previously, this action is not a “regulatory action” as defined by Executive Order 12866. As a result, this action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) and Executive Order 13211 (66 FR 28355, May 22, 2001). In addition, this order also does not require any special considerations under Executive Order 12898 (59 FR 7629, February 16, 1994).

F. National Technology Transfer and Advancement Act

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA), (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.* does not apply because this action is not a rule as that term is defined in 5 U.S.C. 804(3).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Difenzoquat, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 12, 2012.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.